# Complete Summary

## GUIDELINE TITLE

Aspirin for the prevention of cardiovascular disease: U.S. Preventive Services Task Force recommendation statement.

## BIBLIOGRAPHIC SOURCE(S)

US Preventive Services Task Force. Aspirin for the prevention of cardiovascular disease: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2009 Mar 17;150(6):396-404. PubMed

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: U.S. Preventive Services Task Force. Aspirin for the primary prevention of cardiovascular events: recommendations and rationale. Ann Intern Med 2002 Jan 15;136(2):157-60. [15 references]

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

Cardiovascular disease, including coronary heart disease, stroke and peripheral vascular disease

### GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Prevention
Risk Assessment

## CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine
Preventive Medicine

## INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

## GUIDELINE OBJECTIVE(S)

- To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendations and supporting evidence on the use of aspirin for the primary prevention of cardiovascular disease
- To update the 2002 recommendations on the use of aspirin for the primary prevention of cardiovascular events

## TARGET POPULATION

Adult men and women without a history of coronary heart disease or stroke

## INTERVENTIONS AND PRACTICES CONSIDERED

Aspirin prophylaxis

## MAJOR OUTCOMES CONSIDERED

**Key Question 1a**: Does aspirin use in women without known cardiovascular disease decrease coronary heart events, strokes, death from coronary heart events or strokes, or all-cause mortality?

**Key Question 1b**: Does aspirin use in men without known cardiovascular disease decrease coronary heart events, strokes, death from coronary heart events or strokes, or all-cause mortality?

**Key Question 2a**: Does aspirin use in women increase gastrointestinal bleeding or hemorrhagic strokes?

: Does aspirin use in men increase gastrointestinal bleeding or hemorrhagic strokes?

# METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

**Note from the National Guideline Clearinghouse (NGC)**: A review of the literature was prepared by the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

### Data Sources and Searches

For evidence on the benefits of aspirin for the primary prevention of cardiovascular disease (CVD) events (Key Question 1), AHRQ staff performed a literature search in PubMed using the following Medical Subject Heading (MeSH) terms: "aspirin" and "cardiovascular diseases." For evidence on the harms of aspirin for the primary prevention of CVD events (Key Question 2), the following MeSH terms were used: "aspirin," "cardiovascular diseases," "gastrointestinal hemorrhage," and "cerebral hemorrhage." AHRQ staff searched for studies published between January 1, 2001 and August 28, 2008. The literature search was limited to English language studies, human studies, non-pregnant adults, and the following study types for benefits: randomized controlled trial (RCT), meta-analysis, and systematic review. For evidence on harms the search was limited to the following study types: RCT, case control, meta-analysis, and systematic review. In addition to the literature search, AHRQ staff looked for other relevant studies in the Cochrane database and through the examination of reference lists from included and other important articles and through consultation with experts.

### Study Selection

Two reviewers independently reviewed the titles, abstracts, and full articles and selected articles on the basis of predefined inclusion criteria. Disagreements on inclusion were resolved by consensus or the involvement of a third reviewer if necessary. In general, studies were included that evaluated aspirin versus control for the primary prevention of cardiovascular disease events in adults, had a study population of patients without a history of CVD or who were not at very high risk for CVD (such as patients with atrial fibrillation) and was generalizable to the U.S. primary care population, and calculated risk estimates for 1 of the following outcomes: myocardial infarction, stroke, death from myocardial infarction or stroke, or all-cause mortality for benefits and gastrointestinal bleeding, serious bleeding episodes, hemorrhagic stroke, or cerebral hemorrhage for harms. Studies that included patients with a history of CVD or patients who were at very high risk for CVD were included only if those studies reported separate results for patients without a history of CVD or who were not at very high risk for CVD.

## NUMBER OF SOURCE DOCUMENTS

The literature search initially identified 726 potentially relevant articles (see Figure 2 in the Evidence Synthesis [see the "Availability of Companion Documents" field]). Most studies were excluded because either the sample population comprised only patients at very high risk for CVD or with a history of CVD or the study did not evaluate aspirin for the primary prevention of CVD. Studies that

were duplicates or provided no new information, were not of appropriate study design, or did not report outcomes of interest were also excluded. Four studies were ultimately included. The 4 studies provided information on both benefits and harms.

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

**Note from the National Guideline Clearinghouse (NGC)**: A review of the literature was prepared by the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

### Data Extraction and Quality Assessment

Two reviewers independently abstracted and quality-rated the included articles. The following data were extracted from the studies: geographic location, duration of therapy, proportion of female subjects, dosage, control, blinding, outcome adjudication, additional therapies, demographics, and effect estimates on the previously listed outcomes. The quality of the individual studies was evaluated using previously published USPSTF criteria on internal and external validity (see Table 1 in the Evidence Synthesis [see the "Availability of Companion Documents" field]). RCTs were evaluated on adequacy of randomization; maintenance of similar groups (includes attrition, crossovers, adherence, contamination); loss to follow-up; equality, reliability, and validity of measurements; clarity of intervention definitions; and appropriateness of outcomes. Systematic reviews were evaluated on comprehensiveness of sources considered, search strategy used, explicit selection criteria, standard appraisal of included studies, validity of conclusions, recency, and relevance. Studies of poor quality were excluded. AHRQ staff determined generalizability of study sample to the United States by consensus of 3 reviewers after discussions with the USPSTF on similarities between the healthcare system in the study country and that of the United States. Considerations about whether a population would be similar to the U.S. population include the baseline risk of cardiovascular disease, general health status of the population, and the availability of acute medical care and treatment in a health system with available tertiary care centers.

### Data Synthesis

The studies were synthesized qualitatively and organized by key question. AHRQ staff did not synthesize quantitatively because of the availability of a good quality meta-analysis by Berger and colleagues. The results of this meta-analysis are discussed in the Results section of the Evidence Synthesis (see the "Availability of Companion Documents" field).

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Balance Sheets
Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

**Table 1. U.S. Preventive Services Task Force Recommendation Grid***

**Table 1. U.S. Preventive Services Task Force Recommendation Grid***

| Certainty of Net Benefit | Magnitude of Net Benefit | | | |
|---|---|---|---|---|
| | Substantial | Moderate | Small | Zero/Negative |
| High | A | B | C | D |
| Moderate | B | B | C | D |
| Low | Insufficient | | | |

**A*, *B*, *C*, *D*, and *I (Insufficient)* represent the letter grades of recommendation or statement of insufficient evidence assigned by the U.S. Preventive Services Task Force after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the Task Force seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the Task Force considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist us in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the Task Force process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the Task Force's overall assessment of evidence was described as good, fair, or poor. The Task Force realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the Task Force's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the Task Force makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The Task Force must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that 1 of the key questions in the analytic framework refers to the potential harms of the preventive service. The Task Force considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the Task Force assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The Task Force would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the

general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The Task Force would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see "Availability of Companion Documents" field) summarizes the current terminology used by the Task Force to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF et al., Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875.[5 references].

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

### What the United States Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

| Grade | Grade Definitions | Suggestions for Practice |
|---|---|---|
| A | The USPSTF recommends the service. There is high certainty that the net benefit is substantial. | Offer or provide this service. |
| B | The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. | Offer or provide this service. |
| C | The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small. | Offer or provide this service only if there are other considerations in support of the offering/providing the service in an individual patient. |
| D | The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. | Discourage the use of this service. |
| I Statement | The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined. | Read "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms. |

**USPSTF Levels of Certainty Regarding Net Benefit**

**Definition**: The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

| Level of Certainty | Description |
|---|---|
| High | The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies. |
| Moderate | The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:<br><br>• The number, size, or quality of individual studies<br>• Inconsistency of findings across individual studies<br>• Limited generalizability of findings to routine primary care practice<br>• Lack of coherence in the chain of evidence<br><br>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. |
| Low | The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:<br><br>• The limited number or size of studies<br>• Important flaws in study design or methods<br>• Inconsistency of findings across individual studies<br>• Gaps in the chain of evidence<br>• Findings not generalizable to routine primary care practice<br>• A lack of information on important health outcomes<br><br>More information may allow an estimation of effects on health outcomes. |

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Peer Review: Before the U.S. Preventive Services Task Force makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft systematic evidence review to 4 to 6 external experts and to federal agencies and professional and disease-based health organizations with interests in the topic. They ask the experts to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the Task Force in memo form. In this way, the Task Force can consider these external comments and a final version of the systematic review before it votes on its recommendations about the service. Draft recommendations are then circulated for comment from reviewers representing professional societies, voluntary organizations and Federal agencies. These comments are discussed before the whole U.S. Preventive Services Task Force before final recommendations are confirmed.

Recommendations of Others: Recommendations related to aspirin for primary prevention of heart disease from the following groups were discussed: the American Diabetes Association, the American Heart Association, and the American Stroke Association.

# RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the Levels of Certainty regarding Net Benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

### Summary of Recommendations and Evidence

- The USPSTF recommends the use of aspirin for men age 45 to 79 years when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm due to an increase in gastrointestinal hemorrhage. See the "Clinical Considerations" section below for discussion of benefits and harms. **This is an A recommendation**.
- The USPSTF recommends the use of aspirin for women age 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage. See the "Clinical Considerations" section below for discussion of benefits and harms. **This is an A recommendation**.
- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of aspirin for cardiovascular disease prevention in men and women 80 years or older. **This is an I statement**.

See the "Clinical Considerations" section below for suggestions for practice regarding the I statement.

- The USPSTF recommends against the use of aspirin for stroke prevention in women younger than 55 years and for myocardial infarction prevention in men younger than 45 years. **This is a D recommendation**.

## Clinical Considerations

### Patient Population Under Consideration

These recommendations apply to adult men and women without a history of coronary heart disease or stroke.

### Assessment of Risk for Cardiovascular Disease

*Men*

The net benefit of aspirin depends on the initial risk for coronary heart disease events and gastrointestinal bleeding. Thus, decisions about aspirin therapy should consider the overall risks for coronary heart disease and gastrointestinal bleeding.

Risk assessment for coronary heart disease should include ascertainment of risk factors: age, diabetes, total cholesterol levels, high-density lipoprotein cholesterol levels, blood pressure, and smoking.

Figure 2 in the original guideline document shows the estimated number of myocardial infarctions prevented according to coronary heart disease risk level for men age 45 to 79 years—the age range with the potential for substantial net benefit from the use of aspirin. It also shows that the coronary heart disease risk level at which the absolute number of myocardial infarctions prevented by the use of aspirin is greater than the absolute number of gastrointestinal bleeding episodes and hemorrhagic strokes caused by aspirin therapy increases with age. The estimates in Figure 2 of the original guideline document were developed assuming that the men are not currently taking nonsteroidal anti-inflammatory drugs (NSAIDs) and are without other conditions that increase the risk for gastrointestinal bleeding (see below). Furthermore, the decision about the exact level of risk at which the potential benefits outweigh potential harms is an individual one. Some men may decide that avoiding a myocardial infarction is of great value, and that having a gastrointestinal bleeding event is not a major problem. The latter group would probably decide to take aspirin at a lower coronary heart disease risk level than men who are more afraid of gastrointestinal bleeding. Men who have a high likelihood of benefiting with little potential for harm should be encouraged to consider aspirin. Conversely, aspirin use should be discouraged among men who have little potential of benefiting from the therapy or have a high risk for gastrointestinal bleeding.

Shared decision making should be encouraged with men for whom the potential benefits and risks for serious bleeding are more closely balanced (see Figure 3 in the original guideline document). This discussion should explore the potential benefits and harms and patient preferences. As the potential benefit increases above potential harms, the recommendation to take aspirin should become stronger.

Evidence on the benefits in men younger than 45 years is limited, and the potential benefit in this age group is probably low because the risk for myocardial infarction is very low.

*Women*

The net benefit of aspirin depends on the initial risks for stroke and gastrointestinal bleeding. Thus, decisions about aspirin therapy should consider the overall risk for stroke and gastrointestinal bleeding.

Risk factors for stroke include age, high blood pressure, diabetes, smoking, a history of cardiovascular disease, atrial fibrillation, and left ventricular hypertrophy. Tools for estimation of stroke risk are available (such as the calculator available at www.westernstroke.org/PersonalStrokeRisk1.xls).

Figure 4 in the original guideline document shows the estimated number of strokes prevented according to stroke risk level in women age 55 to 79 years—the age range for which evidence shows that there could be substantial potential net benefit of aspirin use. It also shows that the stroke risk level at which the absolute number of strokes prevented is greater than the absolute number of gastrointestinal bleeding events caused increases with age. The estimates in Figure 4 in the original guideline document were developed assuming that women are not currently taking NSAIDs and are without other conditions that increase the risk for gastrointestinal bleeding (see the Risk for Gastrointestinal Bleeding section below). Furthermore, the decision about the exact stroke risk level at which the potential benefits outweigh harms is an individual one. Some women may decide that avoiding a stroke is of great value but experiencing a gastrointestinal bleeding event is not a major problem. These women would probably decide to take aspirin at a lower stroke risk level than those who are more afraid of a bleeding event. Women who have little potential of benefiting from aspirin therapy or have a high risk for gastrointestinal bleeding should be discouraged from taking aspirin.

Shared decision making should be encouraged with women for whom the potential benefits and risks for serious bleeding are more closely balanced (Figure 3 in the original guideline document). This discussion should explore potential benefits and harms and patient preferences. As the potential stroke reduction benefit increases above the potential harms, the recommendation to take aspirin should become stronger.

Evidence on benefits in women younger than 55 years is limited, and the potential benefit in this age group is probably low because the risk for stroke is very low.

**Assessment of Risk for Gastrointestinal Bleeding**

Evidence shows that the risk for gastrointestinal bleeding with and without aspirin use increases with age. For the purposes of making this recommendation, the USPSTF considered age and sex to be the most important risk factors for gastrointestinal bleeding. Other risk factors for bleeding include upper gastrointestinal tract pain, gastrointestinal ulcers, and NSAID use. NSAID therapy combined with aspirin approximately quadruples the risk for serious gastrointestinal bleeding compared with the risk with aspirin alone. The rate of

serious bleeding in aspirin users is approximately 2 to 3 times greater in patients with a history of a gastrointestinal ulcer. Men have twice the risk for serious gastrointestinal bleeding than women. These risk factors increase the risk for bleeding substantially and should be considered in the overall decision about the balance of benefits and harms of aspirin therapy. Enteric-coated or buffered preparations do not clearly reduce the adverse gastrointestinal effects of aspirin. Uncontrolled hypertension and concomitant use of anticoagulants also increase the risk for serious bleeding.

**Treatment**

The optimum dose of aspirin for preventing cardiovascular disease events is not known. Primary prevention trials have demonstrated benefits with various regimens, including dosages of 75 and 100 mg/d and 100 and 325 mg every other day. A dosage of approximately 75 mg/d seems as effective as higher dosages. The risk for gastrointestinal bleeding may increase with dose.

**Intervention Intervals**

Although the optimal timing and frequency of discussions related to aspirin therapy are unknown, a reasonable option might be every 5 years in middle age and later and also whenever other cardiovascular risk factors are detected.

**Suggestions for Practice Regarding the I Statement**

The incidence of myocardial infarctions and strokes are high in persons 80 years or older and thus the potential benefit of aspirin is large. The relationship between increasing age and gastrointestinal bleeding is also well established and thus the potential harms are also large. The net benefit of aspirin use in persons older than 80 years is probably best in those without risk factors for gastrointestinal bleeding (other than older age) and in those who could tolerate a gastrointestinal bleeding episode (for example, those with normal hemoglobin levels, good kidney function, and easy access to emergency care). Clinicians should inform patients about the adverse consequences of gastrointestinal bleeding because they might be mitigated by a patient's early recognition of the signs and symptoms of bleeding (that is, dark stools, vomiting blood, bright red blood per rectum, syncope, and lightheadedness). If clinicians decide to prescribe aspirin in adults older than 80 years, they should do so only after a discussion with the patient that includes the potential harms and uncertain benefits.

**Useful Resources**

The USPSTF made recommendations on other interventions for the primary and secondary prevention of cardiovascular disease, including recommendations on screening for abdominal aortic aneurysms, carotid artery stenosis, coronary heart disease, high blood pressure, lipid disorders, and peripheral arterial disease. These are available at www.preventiveservices.ahrq.gov.

**Definitions**:

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| C | The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small. | Offer or provide this service only if there are other considerations in support of the offering/providing the service in an individual patient. |
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| Level of Certainty | Description |
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| | constrained by factors such as:<br><br>• The number, size, or quality of individual studies<br>• Inconsistency of findings across individual studies<br>• Limited generalizability of findings to routine primary care practice<br>• Lack of coherence in the chain of evidence<br><br>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. |
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### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

#### Benefits of Preventive Medication

The USPSTF found good evidence that aspirin decreases the incidence of myocardial infarctions in men and ischemic strokes in women.

### POTENTIAL HARMS

#### Harms of Preventive Medication

The USPSTF found good evidence that aspirin increases the incidence of gastrointestinal bleeding and fair evidence that aspirin increases the incidence of hemorrhagic strokes.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about preventive care services for patients without recognized signs or symptoms of the target condition.
- Recommendations are based on a systematic review of the evidence of the benefits and harms and an assessment of the net benefit of the service.
- The USPSTF recognizes that clinical or policy decisions involve more considerations than this body of evidence alone. Clinicians and policy-makers should understand the evidence but individualize decision making to the specific patient or situation.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the Agency for Healthcare Research and Quality will make all U.S. Preventive Services Task Force (USPSTF) products available through its Web site. The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access U.S. Preventive Services Task Force materials and adapt them for their local needs. Online access to U.S. Preventive Services Task Force products also opens up new

possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

### IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Personal Digital Assistant (PDA) Downloads
Pocket Guide/Reference Cards
Tool Kits

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

US Preventive Services Task Force. Aspirin for the prevention of cardiovascular disease: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2009 Mar 17;150(6):396-404. PubMed

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

## DATE RELEASED

1996 (revised 2009)

## GUIDELINE DEVELOPER(S)

United States Preventive Services Task Force - Independent Expert Panel

## GUIDELINE DEVELOPER COMMENT

The U.S. Preventive Services Task Force (USPSTF) is a Federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or DHHS agencies.

## SOURCE(S) OF FUNDING

United States Government

## GUIDELINE COMMITTEE

U.S. Preventive Services Task Force

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**Members of the Task Force at the time this recommendation was finalized. For a list of current Task Force members, go to www.ahrq.gov/clinic/uspstfab.htm.*

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The U.S. Preventive Services Task Force has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. Task Force members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: U.S. Preventive Services Task Force. Aspirin for the primary prevention of cardiovascular events: recommendations and rationale. Ann Intern Med 2002 Jan 15;136(2):157-60. [15 references]

## GUIDELINE AVAILABILITY

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site and the Annals of Internal Medicine Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

Evidence Reviews:

- Wolff T, Miller T, Ko S. Aspirin for the primary prevention of cardiovascular events: an update of the evidence. Rockville, Maryland: Agency for Healthcare Research and Quality, 2009 Mar. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.
- Wolff T, Miller T, Ko S. Aspirin for the primary prevention of cardiovascular events: an update of the evidence for the USPSTF. Ann Intern Med. 2009;150:405-10. Electronic copies: Available from the Annals of Internal Medicine Web site.

The following is also available:

- Aspirin for the prevention of cardiovascular disease clinical summary of the U.S. Preventive Services Task Force recommendation. 2009. 1 p. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.

Background Articles:

- Barton M et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann Intern Med. 2007;147:123-127.

- Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med. 2007;147:117-122. [2 references]
- Sawaya GF et al., Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875. [5 references].

Electronic copies: Available from U.S. Preventive Services Task Force (USPSTF) Web site.

The following is also available:

- The guide to clinical preventive services, 2008. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2008. 243 p AHRQ Publication No. 08-05122. Electronic copies available from the AHRQ Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Print copies: Available from the Agency for Healthcare Research and Quality Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

The Electronic Preventive Services Selector (ePSS), available as a PDA application and a web-based tool, is a quick hands-on tool designed to help primary care clinicians identify the screening, counseling, and preventive medication services that are appropriate for their patients. It is based on current recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

**PATIENT RESOURCES**

The following are available:

- Summaries for patients. What aspirin dose is safest and most effective for preventing heart disease? Ann Intern Med 2009 150:I-22. Available from the Annals of Internal Medicine Web site.
- Men: Stay Healthy at Any Age – Checklist for Your Next Checkup. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 07-IP006-A. February 2007. Electronic copies: Available in English and Spanish from the USPSTF Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.
- Women: Stay Healthy at Any Age – Checklist for Your Next Checkup. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 07-IP005-A. February 2007. Electronic copies: Available in English and Spanish from the USPSTF Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

Myhealthfinder is a new tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at www.healthfinder.gov.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

### NGC STATUS

This NGC summary was completed by ECRI on January 3, 2002.The information was verified by the guideline developer as of January 8, 2002. This NGC summary was updated by ECRI Institute on March 12, 2009. The updated information was verified by the guideline developer on June 30, 2009.

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